



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

297 Plus Park Blvd.
Nashville, TN 37217

April 16, 1998

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER-98-NSV-09

FACILITY ID# 115089

Gary Gore
Administrator
Marshall Medical Center North
8000 Hwy. 69
Guntersville, AL 35796

Dear Mr. Gore:

Your facility was inspected on April 1, 1998 by a representative of the State of Alabama, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms: [REDACTED]

Level 2

Measured darkroom fog exceeded 0.05 (the measured fog level was 0.12):
Room = ONE.

These specific deficiencies appear on the List of Observations which was faxed to your facility on April 13, 1998. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

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If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

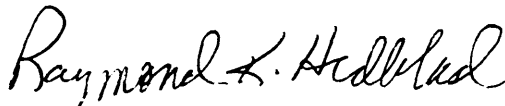
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. If you should have any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, C.S.O., at 615/781-5380, extension 144.

Sincerely,



Raymond K. Hedblad
Director, Nashville District

RKH/ks

cc: State of Alabama